

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into by and among the United States Attorney’s Offices for the Middle District of Florida, District of Maryland, and Western District of Washington, acting on behalf of the United States Department of Justice, the U.S. Attorney’s Offices for all judicial districts of the United States, and the Drug Enforcement Administration (“DEA”) (collectively the “United States”), and Cardinal Health, Inc. and all of its subsidiaries and affiliates (collectively “Cardinal”) (each a “Party” and collectively the “Parties”).

RECITALS

A. Cardinal owns or operates (or has previously owned or operated) twenty-eight (28) distribution centers that are or were registered with DEA as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.* (Controlled Substances Act or “CSA”) (each a “Distribution Center” and collectively the “Distribution Centers”).

B. In determining whether to register an applicant to distribute Schedule II-V controlled substances, the Attorney General, acting through the DEA, must consider the applicant’s maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels. 21 U.S.C. § 823(b)(1) and (e)(1).

C. Section 1301.74(b) of Title 21 of the Code of Federal Regulations requires registrants to operate a system to identify suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered.

D. Distributors are required to execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA “Form 222” order forms and their electronic equivalent for Schedules I

and II controlled substances according to the provisions of 21 U.S.C. § 828 and Part 1305 of Title 21 of the Code of Federal Regulations.

E. Cardinal acknowledges that all of its DEA-registered Distribution Centers were and are required to comply with the CSA and the regulations promulgated thereunder, including the requirements described above in paragraphs C-D.

F. In September 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA ("2008 MOA"). The 2008 MOA resolved allegations related to alleged failures by Cardinal to maintain effective controls against diversion of controlled substances at certain Cardinal distribution centers, including those located in Lakeland, Florida, Swedesboro, New Jersey, and Auburn, Washington.

G. On February 2, 2012, the DEA, by its then-Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal's distribution facility in Lakeland, Florida ("Cardinal Lakeland"), alleging, among other things, that:

1. Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as evidenced by sales to certain customers of Cardinal;
2. Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and
3. Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacy customers, including its retail chain pharmacy customers, to ensure that controlled substances were not diverted into other than legitimate channels.

H. The DEA called for Cardinal to show cause why the DEA registration of Cardinal Lakeland should not be revoked. *See* In the Matter of Cardinal Health, Inc., DEA Docket No. 12-32.

I. To avoid the uncertainty and expense of litigating the above-referenced revocation proceeding to its conclusion, Cardinal and the DEA entered into an Administrative Memorandum of Agreement in May 2012. That agreement specifically reserved the United States' right to pursue civil action for conduct including that described in paragraphs G.1-G.3 above.

J. The United States Attorney's Offices for the Middle District of Florida, the District of Maryland, and the Western District of Washington conducted civil investigations with the assistance of the Drug Enforcement Administration's Orlando District Office, Baltimore District Office, and Seattle Division into alleged failures by Cardinal to inform the DEA of suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b).

K. The United States contends, as the DEA contended during the revocation proceeding referenced in paragraph H above, that Cardinal failed to inform the DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b). The United States contends that these violations subject Cardinal to civil penalties under 21 U.S.C. § 842(a)(5) and (c)(1).

L. Cardinal admits, accepts, and acknowledges Cardinal's responsibility for the following violation of the regulations promulgated by the DEA pursuant to its authority in the Controlled Substances Act:

Between January 1, 2009 and May 14, 2012, Cardinal Lakeland failed to inform DEA that certain orders for controlled substances it received from some customers were suspicious, as required by 21 C.F.R. § 1301.74(b).

Cardinal has implemented changes to its anti-diversion program including those required by the May 2012 Administrative Memorandum of Agreement.

To avoid the delay, expense, inconvenience, and uncertainty of litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Paragraphs A-L set forth above are fully adopted herein.
2. For purposes of this Agreement, "Covered Conduct" shall mean the following:
 - (i) Failure, between January 1, 2009 and the Effective Date of this Agreement, by Cardinal to timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. § 1301.74(b);
 - (ii) Failure, between January 1, 2009 and the Effective Date of this Agreement, by Cardinal to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5); and
 - (iii) Failure, between January 1, 2009 and the Effective Date of this Agreement, by Cardinal to execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA "Form 222" order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. § 828 and 21 C.F.R. Part 1305.

3. Cardinal shall pay to the United States the total sum of \$34,000,000 (thirty-four million dollars, the “Settlement Amount”) within ten (10) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to the written instructions provided to Cardinal by the United States Attorney’s Office for the Middle District of Florida.

4. In consideration of the undertakings of the United States contained herein, Cardinal fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorney’s fees, costs and expenses of every kind and however denominated) that Cardinal has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, and agents related to the investigation, prosecution, and settlement of the Covered Conduct, provided, however, that Cardinal reserves and does not release any liability based on obligations created by this Agreement.

5. In consideration of the undertakings by Cardinal contained herein, and subject to the exceptions in Paragraph 6 below (concerning excluded claims), and conditioned upon Cardinal’s full payment of the Settlement Amount, the United States agrees to:

- (i) Release and refrain from instituting any administrative claims or actions against Cardinal or any of its subsidiaries, affiliates, predecessors, successors, parent companies, and assigns of each, arising from or related to the Covered Conduct;
- (ii) Refrain from filing any action for civil penalties under 21 U.S.C. §§ 842 or 843 based on, arising from, or related to the Covered Conduct; and
- (iii) Adhere to the obligations of and release by the DEA contained in sections II.2 and II.4 of the May 2012 Administrative Memorandum of Agreement.

6. Notwithstanding the releases given in Paragraph 5 of this Agreement, the United States specifically reserves and does not release:

- (i) Any federal criminal liability;
- (ii) Any criminal, civil, or administrative claim arising under Title 26, United States Code (Internal Revenue Code);
- (iii) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- (iv) Any liability based on obligations created by this Agreement; and
- (v) Any claims, rights or remedies of the United States or its departments or agencies related to any acts, omissions or other conduct of Kinray, LLC.

7. Nothing in this Agreement constitutes an Agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

8. This Agreement binds and is intended to benefit only the Parties. This Agreement is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

9. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

10. Each Party and signatory to this Agreement represents that he, she, or it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

11. This Agreement is governed by the laws of the United States. Each Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties will be the United States District Court or, as appropriate, the Court of Federal Claims, in

which the Cardinal Distribution Center at issue is located. For any disputes not related to a specific Distribution Center, the exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Middle District of Florida.

12. For purposes of construing this Agreement, the Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not be construed against any Party for that reason in any subsequent dispute.

13. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Each of the Parties expressly agrees and acknowledges that, in entering this Agreement, it is relying on only the statements and promises expressly set forth in this written Agreement. This Agreement cannot be amended, nor any provisions waived, except in writing and when signed by all Parties to this Agreement.

14. This Agreement is not intended to and does not supersede the obligations contained in the May 2012 Administrative Memorandum of Agreement.

15. The undersigned individuals represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties listed below.

16. This Agreement may be executed in counterparts, including by facsimile, pdf, or other electronic form of signature, each of which constitutes an original and all of which constitute one and the same Agreement.


17. This Agreement is binding on Cardinal and its successors, transferees, heirs, and assigns.

18. The Parties may disclose the existence of and information about this Agreement to the public without restriction.

19. This Agreement is effective (that is, final and binding) on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). The United States agrees to notify Cardinal immediately when the final signatory has executed this Agreement.


[Signatures begin on next page.]

ON BEHALF OF THE UNITED STATES OF AMERICA:




Lacy R. Harwell, Jr.
Chief, Civil Division
Assistant U.S. Attorney
United States Attorney's Office
Middle District of Florida

DATE: 12-9-16



Katherine M. Ho
Chief, Orlando Division
Assistant U.S. Attorney
United States Attorney's Office
Middle District of Florida

DATE: 12/13/2016



Jeffrey V. Walsh
Assistant Special Agent in Charge
DEA Miami Division
Central Florida- Orlando

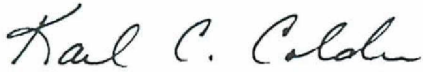
DATE: 12/13/2016

ON BEHALF OF THE UNITED STATES OF AMERICA:



Thomas F. Corcoran
Deputy Chief, Civil Division
Assistant U.S. Attorney
United States Attorney's Office
District of Maryland

DATE: 12/20/16.



Karl C. Colder
Special Agent in Charge
Drug Enforcement Administration
Washington Field Division

DATE: 12/15/16

David East
Assistant U.S. Attorney
United States Attorney's Office
Western District of Washington

DATE: _____

Keith Weis
Special Agent in Charge
Drug Enforcement Administration
Seattle Field Division

DATE: _____

ON BEHALF OF THE UNITED STATES OF AMERICA:

Thomas F. Corcoran
Deputy Chief, Civil Division
Assistant U.S. Attorney
United States Attorney's Office
District of Maryland

DATE: _____

Karl Colder
Special Agent in Charge
Drug Enforcement Administration
Washington Field Division

DATE: _____



David East
Assistant U.S. Attorney
United States Attorney's Office
Western District of Washington

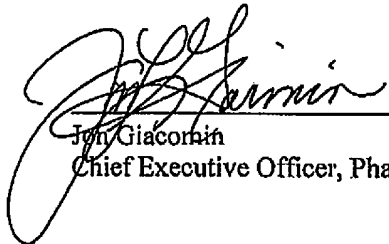
DATE: 12/15/2016



Keith Weis
Special Agent in Charge
Drug Enforcement Administration
Seattle Field Division

DATE: 12-14-2016

ON BEHALF OF CARDINAL HEALTH, INC.:



Jon Giacomini
Chief Executive Officer, Pharmaceutical Segment

DATE: 12/16/2016